

SPL Process Meeting

Meeting Minutes

August 14, 2013

Chair of today's meeting: Mary Beth Wilusz

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

*6: Unmute

Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

Leadership Team -- Discussion Topics:

Agenda:

1. Revisit of D&B data issues topic from 31Jul13 meeting:

- FDA has been seeing a trend that some companies are continuing to ask for manual overrides for their SPL files because of DUNS validation errors. They want to encourage sponsors to work with DUNS to correct the data. Lonnie and John Gardner at FDA have been working with DUNS to resolve issues, because they have received feedback that sponsors are still having issues with resolving their data. They would like us to provide specific examples of what issues sponsors are seeing.
- **Please send examples of difficulties you are experiencing to us me via email.**

Dale lanetti – update from last meeting. Dale (Merck) is part of a pilot program and had a number of issues. Dale sent whole file to D&B to get their help in resolving their issues.

- D&B - compared all data from all sites – so that they could determine the differences.
- Talked through all the issues. D&B is investigating several of their issues. They are going to talk to FDA to determine if there is some flexibility in terms of allowing differences.
- Merck will not change addresses or names, but will make minor changes in addresses if the address is still consistent. Merck also needs several new DUNS numbers because the addresses didn't match up.

2. E-mail with name of D&B contact. Last week, someone sent the name and e-mail address of their D&B account manager to the entire distribution list for the SPL Process Team. Cheryl Ault is not the D&B contact for every drug company. Each company has a different account manager. Please contact D&B to find out who you should work with related to your D&B information.

D&B has recently updated their web site to help sponsors get answers to their DUNS questions. The updated instructions are available on the following URL:

<http://www.dnb.com/government/duns-request/duns-request-guide.html>

Refer to this web site on how to find DUNS numbers and make modifications.

3. Increased requests for “import only” SPL submissions?
 - Prior discussions have indicated some companies have needed to perform a separate “import-only” drug listing using the, while others have not. Based on recent feedback from some companies, it looks like there has been a recent increase in scrutiny at port of entry – and an increase in requests for “import only” drug listings. Does anyone have any recent similar experiences?
 - Dragan (Abbott): They are seeing a change
 - Initially they included API within the final product. However ports are now asking/expecting the API to be drug listed separately.
 - This is difficult when API is coming from a third party.
 - Mary Beth (Merck): They are seeing questions becoming more SPL specific.
 - For finished goods, are port authorities expecting to see NDCs of foreign establishment’s manufacturers?
 - What is being held? Typically, API or bulk in process
 - Many sponsors are also drug listing finished product from foreign manufacturers.
 - Question: has there been any extra training for the port authorities.
3. Any additional questions about SPLr5 email discussion? Is there any impact?
 - Lonnie and Myron discussed this in email. SPLr5 has been used for over 2 years. Backwards compatible. Therefore should be no impact to your routine work.
 - When normative standard? Ballot in September.
4. Labeling question : Have people received requests from review divisions for specific formatting/font requirements for Medication Guides – verdana, 11 point
 - This is happening with more frequency. They are getting more feedback for verdana 11 point. Claim that it is much easier to read in MSWord version. .
 - J&J had same request from multiple review divisions.
 - The recent PLR guidelines specify minimum 10 point font size requirements for printed labeling.
 - GSK and other companies: Received a lot of comments about verdana 11 point.
 - This will be seen more as FDA is doing MSWord to pdf conversions. Need sans serif type font.
 - Want 6 point width – standard width sizes.
 - Especially important for visually impaired. There is a website with recommendations on fonts that can be used with visually impaired people. See below.

<http://www.aph.org/edresearch/lpguide.htm>

<http://www.aph.org/products/aphont/>

5. Since the upgrade last weekend, Is anyone else having to request manual overrides for supposed changes to the product data elements that haven't been changed?
 - People are seeing various issues/changes in validation rules lately .
6. Changes to the product name, but nothing else changes (formulation of the drug, indications or directions), do we have to change the NDC?
 - Yes. This is one of the things that causes a change to the NDC code.
 - The situation that prompted this question is actually a correction to a name that was entered wrong when the SPL was initially entered.
 - Suggest to contact the DRLS group to see if they are OK with correcting it. They will want to look at the trade labeling to verify that there is no change to the actual product or labeling.
 - If DRLS is in agreement with the correction, Lonnie may be willing to override once the DRLS has given their opinion.
7. Federal Register: They had withdrawn several ANDAs in 2011. Now FDA is requesting that they update their labeling. Would like consult on whether they really have to submit the labeling changes.
 - Received notification that withdrawals have been accepted and products have been removed from DailyMed and the Orange Book. There are several safety changes after the product was withdrawn.
 - Since the product has been withdrawn (2 years ago),there is nothing they can do. But they should still respond back to the FDA with their rationale.